	I and the second						
1	R. Brent Wisner, Esq. (SBN: 276023)						
2	rbwisner@baumhedlundlaw.com Pedram Esfandiary, Esq. (SBN: 312569)						
3	pesfandiary@baumhedlundlaw.com						
4	BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C. 10940 Wilshire Blvd., Suite 1600 Los Angeles, CA 90024 Tel: (310) 207-3233						
5							
6	Fax: (310) 820-7444						
7	Attorneys for Plaintiff						
8							
9	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA						
10	NORTHERN DIS	TRICT OF CALIFORNIA					
11	RS, a minor represented by mother and	Case No. 3:22-cv-03034					
12	guardian ad litem Ashley Scarlott						
13	Plaintiff,	COMPLAINT					
14	v.	DEMAND FOR JURY TRIAL					
15	Nurture, Inc.; and Gerber Products Company,						
16							
17	Defendants.						
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## TABLE OF CONTENTS

			Page	Э		
TABLE	E OF C	ONTEN	NTS	i		
INTRO	DUCT	ION		1		
PARTIES2						
	I.	Plainti	ff	2		
	II.	Defend	lants	3		
JURISI	DICTIC	)N ANI	O VENUE	3		
FACTUAL ALLEGATIONS4						
	I.	Rising	Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods	1		
	II.	Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods, Sparking National Outrage		5		
	III.	Danger	rs of Toxic Heavy Metals to Babies and Children	7		
		A.	Exposure to Toxic Heavy Metals Has Been Consistently Associated with Autism in Pediatric Populations	3		
	IV.	Heavy	lants Knowingly Sold Baby Foods Containing Dangerous Levels of Toxic Metals and Knew or Should Have Known of the Risks of Such Exposures in en	2		
		A.	Nurture	3		
		B.	Gerber Regularly Uses Ingredients High in Toxic Heavy Metals in its Baby Food	5		
	V.	Exemp	olary / Punitive Damages Allegations10	5		
PLAIN'	TIFF-S	PECIF	IC ALLEGATIONS17	7		
CAUSES OF ACTION19						
COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN19						
COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT22						
	COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT24					
	COUNT IV: NEGLIGENCE – FAILURE TO WARN26					
	COUNT V: NEGLIGENT PRODUCT DESIGN					
	COUN	T VI: N	NEGLIGENT MANUFACTURING	1		

COUNT VII: NEGLIGENT MISREPRESENTATION	32
PRAYER FOR RELIEF	33
COMPLAINT	
	COUNT VII: NEGLIGENT MISREPRESENTATION  JURY TRIAL DEMAND  PRAYER FOR RELIEF  ii  COMPLAINT

#### **INTRODUCTION**

- 1. This case involves two manufacturers—namely Nurture, Inc. and Gerber Products Company ("Defendants" or "Defendant Baby Food Manufacturers")—that *knowingly* sold baby food products ("Baby Foods") which contain dangerous levels of toxic heavy metals—mercury, lead, and arsenic (collectively "Toxic Heavy Metals"), which are all known to be severe neurotoxins—and how such toxic exposures substantially contributed to Plaintiff developing lifelong brain damage and neurodevelopmental disorders. Plaintiff RS ("Plaintiff"), represented in this lawsuit by his mother and guardian *ad litem*, is a four-year-old boy who lives with debilitating Autism Spectrum Disorder ("ASD") because he consumed poisonous Baby Foods manufactured and sold by these Defendants. This case seeks to hold the Defendant Baby Food Manufacturers accountable for their reprehensible conduct and ensure they are punished for permanently affecting Plaintiff's ability to live a fulfilling life.
- 2. That Defendants' Baby Foods are laced with staggering amounts of Toxic Heavy Metals recently made headlines following research and a Congressional investigation. In February 2021, the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform released a report containing shocking details of Defendants' tainted Baby Foods based on the submission of internal test results and company documents. Specifically, the Subcommittee found that Defendants sell Baby Foods containing as much as 180 parts per billion ("ppb")<sup>2</sup> inorganic arsenic, 641 ppb lead, and 10 ppb mercury, far eclipsing domestic and international regulatory standards. By way of comparison, the U.S. Food and Drug Administration ("FDA") has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic and 5 ppb lead, and the U.S. Environmental Protection Agency ("EPA") has capped the

<sup>&</sup>lt;sup>1</sup> To be clear, the type of organic mercury at issue here is methylmercury found in food, not ethylmercury contained in the thimerosal vaccine. Ethylmercury is rapidly excreted from the body and is not considered as toxic as methylmercury. Ethylmercury and vaccines are irrelevant to this litigation.

<sup>&</sup>lt;sup>2</sup> Ppb (or ppbm) is used to measure the concentration of a contaminant in soils, sediments, and water. 1 ppb equals 1 μg (microgram) of substance per kg of solid (μg/kg). For the average baby weighing approximately 3kg, the quantities of Toxic Heavy Metals found in Defendants' Baby Foods, as explained below, pose significant health risks.

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I.

allowable level of mercury in drinking water at 2 ppb. With a chilling note the Subcommittee concluded that "[m]anufacturers *knowingly* sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever."<sup>3</sup> (emphasis added). Indeed, following the Congressional findings, FDA-funded testing confirmed the alarming levels of heavy metals found in Defendant Gerber's infant rice cereal.<sup>4</sup>

- 3. The high levels of Toxic Heavy Metals found in Defendants' Baby Foods are, in part, a function of the ingredients used by Defendants to manufacture their Baby Foods, the setting of dangerously inflated internal limits which Defendants willingly flouted, disregard of regulatory standards, and corporate policies which failed to test finished products before market distribution, purchase by unknowing parents, and consumption by vulnerable infants.
- 4. Defendants' malicious recklessness and callous disregard for human life has wreaked havoc on the health of countless vulnerable children, all so that Defendants could maximize profits while deliberately misleading parents regarding the safety of their Baby Foods. Accordingly, this lawsuit will not only ensure that Plaintiff is duly compensated for his tragic injuries and Defendants punished, but that future generations are protected from the poisonous products that Defendants pander as "food".

### **PARTIES**

### Plaintiff

5. Plaintiff is a citizen of California and no other state.

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf.

<sup>&</sup>lt;sup>3</sup> Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021) ("Subcommittee Report 1") at 59, available at: <a href="https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf">https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf</a>.

<sup>&</sup>lt;sup>4</sup> Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, *New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods* (September 29, 2021) ("Subcommittee Report II") at 2-5, 12-16, available at:

## II. Defendants

- 6. Defendant Nurture, Inc ("Nurture"), is a citizen of Delaware and New York with its principal place of business located at 40 Fulton St, 17<sup>th</sup> Floor, New York, NY 10038-1850. Nurture owns Happy Family Brands (including Happy Family Organics) and sells Baby Foods under the brand name "HappyBaby". Nurture classifies its HappyBaby range of products according to three categories: "baby", "tot", and "mama". The "baby" category is comprised of foods, including "starting solids", intended for age groups 0-7+ months, the "tot" category covers 12+ months, and "mama" includes infant formulas for newborn babies. At all relevant times, Nurture has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of HappyBaby within this judicial district.
- 7. Defendant Gerber Products Company ("Gerber") is a citizen of Michigan with its principal place of business located at 445 State Street, Fremont, MI 49413-0001. Gerber sells Baby Foods under the brand name "Gerber". Gerber organizes its products into broad categories of "formula", "baby cereal", "baby food", "snacks", "meals & sides" "beverages" and "organic". At all relevant times, Gerber has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

#### **JURISDICTION AND VENUE**

- 8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess of \$75,000, exclusive of interest and costs.
- 9. This Court has personal jurisdiction over Defendants insofar as both Defendants are authorized and licensed to conduct business in the State of California, maintain and carry on systematic and continuous contacts in this judicial district, regularly transact business within this judicial district, and regularly avail themselves of the benefits of this judicial district.
- 10. Additionally, Defendants caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this district by acts and omissions outside this district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving

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substantial revenue from goods used or consumed and services rendered in this judicial district.

Venue is proper before this Court pursuant to 28 U.S.C. § 1391 because a substantial 11. part of the events or omissions giving rise to this claim occurred within this judicial district.

## **FACTUAL ALLEGATIONS**

#### I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods

- 12. In October 2019, an alliance of nonprofit organizations, scientists and donors named "Happy Babies Bright Futures" ("HBBF"), dedicated to designing and implementing "outcomesbased programs to measurably reduce babies' exposures to toxic chemicals"<sup>5</sup>, published a report investigating the presence of Toxic Heavy Metals in baby foods.<sup>6</sup> The HBBF Report tested 168 different baby foods sold on the U.S. market and concluded that "[n]inety-five percent of baby foods tested were contaminated with one or more of four toxic heavy metals—arsenic, lead, mercury and cadmium. All but nine of 168 baby foods contained at least one metal; most contained more than one." Specifically, the HBBF report identified "puffs and other snacks made with rice flour", "[t]eething biscuits and rice rusks", "infant rice cereal", "apple, pear, grape and other fruit juices", and "carrots and sweet potatoes" manufactured by Defendants as particularly high in Toxic Heavy Metals.8
- 13. The results of the HBBF report were consistent with that of the FDA which had, in 2017, detected one or more of the four Toxic Heavy Metals in 33 of 39 types of baby food tested.<sup>9</sup> However, the HBBF reported that "[f]or 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set enforceable limits or issue guidance on maximum safe amounts."<sup>10</sup>

<sup>5</sup> https://www.hbbf.org/solutions.

<sup>&</sup>lt;sup>6</sup> Healthy Babies Bright Futures, What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IO, Including Arsenic and Lead (Oct. 2019) ("HBBF Report"), available at:

www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-

<sup>10/</sup>BabyFoodReport FULLREPORT ENGLISH R5b.pdf). <sup>7</sup> *Id*. at 6.

<sup>&</sup>lt;sup>8</sup> *Id.* at 10-11

<sup>&</sup>lt;sup>9</sup> *Id*. at 6. <sup>10</sup> *Id*. at 6.

1 The HBBF's findings were by no means an outlier. Eight months prior to publication of the HBBF 2 report, a study conducted by scientists at the University of Miami and the Clean Label Project 3 4

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"examined lead and cadmium concentrations in a large convenience sample of US baby foods." 11 The study detected lead in 37% of samples. 12 Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods, II. **Sparking National Outrage** 

- 14. On February 4, 2021, the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, published a report detailing its findings that Toxic Heavy Metals—including arsenic, lead, and mercury—were present in "significant levels" in numerous commercial baby food products.<sup>13</sup> Four companies—Hain, Gerber, Nurture, and Beech-Nut —produced internal testing policies, test results for ingredients and finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits. Three companies—Plum, Walmart, and Sprout—refused to cooperate.<sup>14</sup>
- 15. The Subcommittee reported that the data submitted by the companies unequivocally revealed that a substantial number of their finished products and/or ingredients used to manufacture the Baby Foods are tainted with significant levels of Toxic Heavy Metals, namely inorganic arsenic, lead, and mercury. 15
- 16. Specifically, the Congressional committee concluded that inorganic arsenic was present in Defendants' baby foods. Internal company testing by Defendant Nurture showed that its products contain as much as 180 ppb inorganic arsenic and that the typical baby food product it sold contained 60 ppb inorganic arsenic. Gerber used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic.

<sup>&</sup>lt;sup>11</sup> Gardener, et al., Lead and cadmium contamination in a large sample of United States infant formulas and baby foods, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at: https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub. <sup>12</sup> *Id*.

<sup>&</sup>lt;sup>13</sup> See generally Subcommittee Rpt.

<sup>&</sup>lt;sup>14</sup> Subcommittee Rpt. at 2.

<sup>&</sup>lt;sup>15</sup> *Id*. at 2-3.

<sup>16</sup> *Id*. at 2-4.

<sup>17</sup> See HBBF Rpt. at 19.

- 17. Lead was present in baby foods made by all responding companies. Specifically, Defendant Nurture sold finished baby food products that tested as high as 641 ppb lead. Almost 20% of the finished baby food products that Nurture tested contained over 10 ppb lead. And Defendant Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead.
- 18. Moreover, Nurture sold finished baby food products containing as much as 10 ppb mercury. Gerber rarely tests for mercury in its baby foods. <sup>16</sup> However, independent testing by HBBF of Gerber's Baby Foods confirm that Gerber's products contain as much as 1.79 ppb of mercury. <sup>17</sup>
- 19. These levels greatly surpass the limits allowed by U.S. regulatory agencies. Upon information and belief, there are no FDA regulations governing the presence of Toxic Heavy Metals in the majority of Baby Foods. Indeed, the FDA has only finalized *one* standard—100 ppb inorganic arsenic in infant rice cereal. The quantities of Toxic Heavy Metals in Defendants' Baby Foods far exceed any permissible FDA levels, including the 100 ppb standard for infant rice cereal. To be sure, the FDA has set the maximum contaminant levels ("MCL") in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However, these limits were created in reference to *adult* exposure, not infants. Compared to these thresholds, the test results of the Defendants' Baby Foods and their ingredients are 10 times greater than permitted arsenic levels, 128 times greater than permitted lead levels, and 5 times greater than permitted mercury levels.
- 20. Compounding these troubling findings, Defendants set internal limits for the presence of Toxic Heavy Metals in their foods that were, themselves, dangerously high and then routinely failed to abide by those inadequate standards, as discussed below. For example, the Subcommittee found that Defendant Nurture sold all products tested, *regardless* of how much toxic heavy metal the baby food contained. By company policy, Nurture's toxic heavy metal testing is not intended for consumer safety. The FDA has only finalized one standard—100 ppb inorganic arsenic in infant rice

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cereal—and Nurture set its internal standard for that product 15% higher than the FDA limit, at 115 ppb. 18

21. As found by the Subcommittee, Defendants have willfully sold—and continue to sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels of Toxic Heavy Metals in their products. Discovery will flesh out in greater detail the extent of Toxic Heavy Metals in Defendants' Baby Foods.

## III. Dangers of Toxic Heavy Metals to Babies and Children

- 22. According to the World Health Organization ("WHO"), Toxic Heavy Metals, specifically arsenic, lead, and mercury, pose a "major public health concern" for children. The Occupational Safety and Health Administration ("OSHA") has warned that these metals "may build up in biological systems and become a significant health hazard." Indeed, the Department of Health and Human Services' Agency for Toxic Substances and Disease Registry ("ATSDR") ranks arsenic as number *one* among substances present in the environment that pose the most significant potential threat to human health, followed by lead (second), mercury (third). <sup>21</sup>
- 23. The threat presented by Toxic Heavy Metals to children's health is widely shared by the global scientific community. As one recent study observed, "[t]he implications of heavy metals with regards to children's health have been noted to be more severe compared to adults. The elements' harmful consequences on children health include mental retardation, neurocognitive disorders, behavioral disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given to heavy metals because of their high toxicity potential, widespread use, and prevalence."<sup>22</sup> Children and, even more so, babies have higher exposure to metals compared to adults because they consume more food in relation to their body weight and absorb metals more

<sup>&</sup>lt;sup>18</sup> *Id*. at 4.

<sup>&</sup>lt;sup>19</sup> World Health Organization, *Children's Health and the Environment WHO training Package for the Health Sector* (October 2011), available at: <a href="https://www.who.int/ceh/capacity/heavy\_metals.pdf">https://www.who.int/ceh/capacity/heavy\_metals.pdf</a>.

<sup>&</sup>lt;sup>20</sup> OSHA, *Toxic Metals*, available at: <a href="https://www.osha.gov/toxic-metals">https://www.osha.gov/toxic-metals</a>.

<sup>&</sup>lt;sup>21</sup> ATSDR, *ATSDR's Substance Priority List* (2019), available at: www.atsdr.cdc.gov/spl/index.html#2019spl.

Osman, et al., *Exposure routes and health effects of heavy metals on children*, 32 BIOMETALS 563–573 (2019), available at: <a href="https://link.springer.com/article/10.1007%2Fs10534-019-00193-5#citeas.">https://link.springer.com/article/10.1007%2Fs10534-019-00193-5#citeas.</a>

readily than adults by 40 to 90%.<sup>23</sup> And, the mechanisms needed to metabolize and eliminate heavy metals are comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms and poorer immune systems than adults.<sup>24</sup> For example, liver pathways that in adulthood metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in other organs.<sup>25</sup> According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health effects, "[n]o level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants."<sup>26</sup> Thus, "the major windows of developmental vulnerability occur during infancy and early childhood due to continuing brain development after birth."<sup>27</sup> In short, even small amounts of exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

# **A.** Exposure to Toxic Heavy Metals Has Been Consistently Associated with Autism in Pediatric Populations

24. A chorus of regulators, research agencies and independent scientists are in broad agreement that exposure to heavy metals in early life is causally associated with ASD. The Centers for Disease Control ("CDC") in its toxicological profile of lead specifically observes that "neurodevelopmental effects in children have been associated with [lead]" at different quantities of exposure. At doses of  $\leq 10 \, \mu \text{g/dL}^{29}$ , the agency observed "[a]ltered mood and behaviors that may contribute to learning deficits, including attention deficits, hyperactivity, *autistic behaviors*, conduct

<sup>&</sup>lt;sup>23</sup> Stein, et al., *In harm's way: toxic threats to child development*, 23 J DEV BEHAV PEDIATR.1 S13–S22 (2002).

<sup>| &</sup>lt;sup>24</sup> Gorini, et al., *The Role of Heavy Metal Pollution in Neurobehavioral Disorders: a Focus on Autism* | 1 Rev. J. Autism Dev. Disord. 1, 354–372 (2014), available at:

<sup>23</sup> https://link.springer.com/article/10.1007/s40489-014-0028-3.

<sup>&</sup>lt;sup>25</sup> Del Rio, et al., *A comparison of arsenic exposure in young children and home water arsenic in two rural West Texas communities* 17 BMC PUBLIC HEALTH 850 1-13 (2017), available at: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4808-4.

<sup>&</sup>lt;sup>26</sup> Roni Caryn Rabin, *Some Baby Food May Contain Toxic Metals, U.S. Reports* (NY TIMES, Feb 4. 2021), available at: <a href="https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html">https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html</a>

Gorini, et al. *supra*.
 ATSDR Toxicological Profile for Lead at 133, available at:

https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf.

29 This means effects observed at less than ten micrograms of lead per blood liter.

disorders, and delinquency."<sup>30</sup> The U.S. National Institute of Health ("NIH") concurs, noting that "[p]renatal and early childhood exposure to heavy metals...may be linked to autism spectrum disorder."<sup>31</sup> And, in July 2016, a large consortium consisting of the world's leading epidemiologists, autism experts, and medical organizations published a consensus statement which identified heavy metals such as lead and mercury as "*prime examples* of toxic chemicals that can contribute to...autism spectrum disorder[.]"<sup>32</sup>

- 25. Such conclusions are based upon a substantial body of independent, peer-reviewed research conducted throughout various parts of the world over the last decade which has consistently observed a positive association between exposure to Toxic Heavy Metals and the development of ASD in children and infant populations. The literature is comprised of prospective cohort studies where children's metal exposure is measured in early life and their risk of subsequently developing ASD evaluated; pre-natal studies where pregnant mothers' metal exposure is measured prior to assessing the risk of ASD in later born children; case-control and cross sectional studies where children's metal exposure is measured contemporaneous with ASD diagnoses; as well as metanalyses where individual studies are grouped together to derive an overall picture of the data.
- 26. Repeatedly, the different study types evince a strong association between metal exposure and ASD risk. For example, a 2017 NIH-funded study of twins concluded that "prenatal and early childhood disruption (excess or deficiency) of multiple metals during critical developmental windows is associated with ASD...[and] increases ASD risk and severity"<sup>33</sup> Similarly, a 2019 study and a 2021 study of metal exposure in pregnant mothers and the risk of subsequent ASD diagnosis in children respectively observed that "[arsenic] and [lead] levels in [amniotic fluids] tend to be

<sup>&</sup>lt;sup>30</sup> *Id.* (emphasis added).

<sup>&</sup>lt;sup>31</sup> NIH, *Autism Spectrum Disorder and the Environment* (April 2019), available at: https://www.niehs.nih.gov/health/materials/autism\_spectrum\_disorder\_and\_the\_environment\_508.pd f

<sup>&</sup>lt;sup>32</sup> Bennett, et al., Project TENDR: *Targeting Environmental Neuro-Developmental Risks The TENDR Consensus Statement* 124 ENVIRON. HEALTH. PERSPECT. 7 A118-A122 (2016), available at: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937840/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937840/</a>. (emphasis added).

<sup>&</sup>lt;sup>33</sup> Arora. et al., *Fetal and postnatal metal dysregulation in autism*, 8 NATURE COMM. 1-10, 1, 5 (2017), available at: <a href="https://www.nature.com/articles/ncomms15493">https://www.nature.com/articles/ncomms15493</a>.

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positively associated with ASD risk, suggesting the possible role of prenatal exposure to toxic metals in the ASD development"34 and "[r]esults from the present study show several associations between levels of metals and elements during gestation and ASD...in children. The most notable ones involved arsenic...mercury..., and lead."35

- 27. Such results have been replicated in prospective cohort studies of early life metal exposure, with a 2016 Korean study noting that "[e]ven low blood lead concentrations at 7–8 years of age are associated with more autistic behaviors at 11–12 years of age[.]"<sup>36</sup> Similarly, another prospective Korean study from 2017 "observed that higher blood mercury levels at late pregnancy, in cord blood, and at 2 and 3 years of age were positively associated with autistic behaviors among preschool-age children."37
- 28. Furthermore, smaller human studies from around the world have observed similar results, with a 2018 Chinese study concluding: "[t]he results of this study are consistent with numerous previous studies, supporting an important role for heavy metal exposure, particularly mercury, in the etiology of ASD.<sup>38</sup> Indeed, a 2014 Egyptian study noted that "[1]ead and mercury are

BEHAV. NEUROL. (2015), available at: <a href="https://pubmed.ncbi.nlm.nih.gov/26508811/">https://pubmed.ncbi.nlm.nih.gov/26508811/</a>; Adams, et al., Toxicological Status of Children with Autism vs. Neurotypical Children and the Association with

<sup>&</sup>lt;sup>34</sup> Long, et al., Autism spectrum disorders, endocrine disrupting compounds, and heavy metals in amniotic fluid: a case-control study 10 Mol. Autism 1-19, 15 (2019), available at: https://pubmed.ncbi.nlm.nih.gov/30647876/.

<sup>&</sup>lt;sup>35</sup> Skogheim, et al. Metal and essential element concentrations during pregnancy and associations with autism spectrum disorder and attention-deficit/ hyperactivity disorder in children, 152 ENVIRON. INTL. 1-14, 1 (2021), available at: https://pubmed.ncbi.nlm.nih.gov/33765546/.

<sup>&</sup>lt;sup>36</sup> Kyoung-Nam Kim et al., Low-level lead exposure and autistic behaviors in school-age children 53 EURO TOXICOLOGY 193-200, 193 (2016), available at: https://pubmed.ncbi.nlm.nih.gov/26877220/.

<sup>&</sup>lt;sup>37</sup> Jia Ryu et al., Associations of prenatal and early childhood mercury exposure with autistic behaviors at 5 years of age: the Mothers and Children's Environmental Health (MOCEH) Study, 605-606 SCI. OF THE TOTAL ENVT. 251-257, 251 (2017), available at: https://pubmed.ncbi.nlm.nih.gov/28667852/.

<sup>&</sup>lt;sup>38</sup> Li, et al., Blood Mercury, Arsenic, Cadmium, and Lead in Children with Autism Spectrum Disorder, 181 BIOL TRACE ELEM RES 31-37, 31 (2018), available at: https://pubmed.ncbi.nlm.nih.gov/28480499/; see also Dickerson, et al., Autism spectrum disorder

prevalence and associations with air concentrations of lead, mercury, and arsenic, 188 Environ MONIT. ASSESS. 407 (2016); Mohamed, et al., Assessment of Hair Aluminum, Lead, and Mercury in a Sample of Autistic Egyptian Children: Environmental Risk Factors of Heavy Metals in Autism

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https://pubmed.ncbi.nlm.nih.gov/31630927/.

considered as one of the main causes of autism."<sup>39</sup>

29. On the basis of this robust body of data, several meta-analyses published in recent years report consistent associations between exposure to Toxic Heavy Metals and ASD in children; with the authors of a 2017 meta-analysis specifically concluding: "Results of the current metaanalysis revealed that mercury is an important causal factor in the etiology of ASD."40

30. The fact that such results have been observed in multiple studies, conducted by different researchers, at different times, in different parts of the world, in children of varying ages, and measuring a variety of end-points (including hair, blood, and urine), strongly supports a causal relationship between exposure to Toxic Heavy Metals and the development of ASD in children.

Autism Severity, 151 BIOL. TRACE ELEM. RES 171-180 (2013), available at: https://pubmed.ncbi.nlm.nih.gov/23192845/.

<sup>39</sup> Yassa, H., Autism: A form of lead and mercury toxicity 38 Environ. Tox. & Pharm. 1016-1024 (2014), available at: https://pubmed.ncbi.nlm.nih.gov/25461563/ (emphasis added); see also Filon, et al., Analysis of lead, arsenic and calcium content in the hair of children with autism spectrum disorder 20 BMC PUBLIC HEALTH 1-8 (2020), available at: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-08496-w; Fiore, et al.,

Metal and essential element levels in hair and association with autism severity 57 JOURNAL OF TRACE ELEMENTS IN MEDICINE AND BIOLOGY 99-103 (2020), available at:

<sup>40</sup> Jafari, et al., The association between mercury levels and autism spectrum disorders: A systematic review and meta-analysis, 44 J. Trace Elem. Med. Biol. 289-297, 289 (2017), available at: https://pubmed.ncbi.nlm.nih.gov/28965590/; Saghzadeh & Rezai, Systematic review and meta-

analysis links autism and toxic metals and highlights the impact of country development status: Higher blood and erythrocyte levels for mercury and lead, and higher hair antimony, cadmium, lead,

and mercury, 79 Prog. Neuro-Psychopharmacol. Biol. Psychiatry 340-368 (2017), available at: https://pubmed.ncbi.nlm.nih.gov/28716727/; Wang, et al., Exposure to Inorganic Arsenic and Lead and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis, 21 CHEM RES.

TOXICOL. 32, 1904-1919 (2019), available at: https://pubmed.ncbi.nlm.nih.gov/31549506/; Sulaiman, et al., Exposure to Aluminum, Cadmium, and Mercury and Autism Spectrum Disorder in Children: A

Systematic Review and Meta-Analysis, 33 Chem. Res. Toxicol. 11, 2699-2718 (2020), available at: https://pubmed.ncbi.nlm.nih.gov/32990432/; Yoshimasu, et al., A meta-analysis of the evidence on the impact of prenatal and early infancy exposures to mercury on autism and attention

deficit/hyperactivity disorder in the childhood, 44 NEURO TOXICOL. 121-131 (2014), available at: https://pubmed.ncbi.nlm.nih.gov/24952233/.

## IV. Defendants Knowingly Sold Baby Foods Containing Dangerous Levels of Toxic Heavy Metals and Knew or Should Have Known of the Risks of Such Exposures in Children

- 31. During the time that Defendants manufactured and sold Baby Foods in the United States, the weight of evidence showed that Defendants' Baby Foods exposed babies and children to unsafe levels of Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.
- 32. As discussed above, both independent testing, Defendants' internal evaluations of their Baby Foods, and Defendants' representations and disclosures to the Subcommittee and FDA reveal the presence of substantial amounts of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or should have known that their Baby Foods contain dangerous levels of Toxic Heavy Metals.
- 33. Indeed, independent testing performed in early 2019 demonstrated elevated amounts of Toxic Heavy Metals in Baby Food products on the U.S. market,<sup>41</sup> and the HBBF Report further confirmed such contamination of Defendants' Baby Foods.<sup>42</sup> And, as the Subcommittee found, Defendants continued to sell their Baby Foods even after testing of both ingredients and finished products revealed the presence of substantial amounts of Toxic Heavy Metals.<sup>43</sup>
- 34. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly as it relates to adverse effects on the neurodevelopment of children—have been well known for decades. Defendants, as manufacturers of Baby Foods, are held to the standard of experts responsible for keeping abreast of the latest scientific developments related to the dangers of contaminants in their products. Defendants failed to take action in protecting vulnerable children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk of developing neurodevelopmental disorders such as ASD.
- 35. To be clear, Defendants are able to manufacture Baby Foods that do not pose such a dangerous risk to the health of infants and children by using alternative ingredients, not adding

<sup>&</sup>lt;sup>41</sup> See Gardener, et al., supra.

<sup>&</sup>lt;sup>42</sup> See HBBF Report, supra.

<sup>&</sup>lt;sup>43</sup> See, e.g., Subcommittee Report at 13-14.

certain pre-mix minerals and vitamins high in Toxic Heavy Metals or sampling their ingredients from

presence of Toxic Heavy Metals in their Baby Foods. However, Defendants took no action, continued

other sources. At the very least, Defendants were under a duty to warn unsuspecting parents of the

to sell their products with full knowledge of the risks posed by their Baby Foods, and misled

# consumers regarding the safety of their products, all to the harm of children.

A. Nurture

- 1. Nurture Sells Products Even After Testing Confirms Their High Toxic Heavy Metal Content and Regularly Uses Ingredients High in Toxic Heavy Metals in its Baby Food
- 36. According to internal company documents, Nurture sells products even after testing confirms that they are dangerously high in inorganic arsenic. Nurture sold one such product, Apple and Broccoli Puffs, despite tests results showing it contained 180 ppb inorganic arsenic. <sup>44</sup> An arsenic level of 180 ppb is high by all standards, but it is 80% higher than Nurture's own internal goal threshold of 100 ppb. Nurture routinely sold products that exceeded its internal standards. Twentynine other products that Nurture tested and sold registered over 100 ppb inorganic arsenic. In total, over 25% of the products that Nurture tested for inorganic arsenic, and sold, had inorganic arsenic levels above 100 ppb. <sup>45</sup>
- 37. Moreover, Nurture sold products that tested as high as 641 ppb lead—over six times higher than its internal limit of 100 ppb lead. And Nurture also sold five other products after they tested over 50 ppb lead. Of the 206 finished products that Nurture tested for lead, 16 products registered over 20 ppb lead—exceeding EU standards. And 39 products, or 18.9%, tested over 10 ppb lead. It is not clear that even *one* of Nurture's baby food products registered at or below 1 ppb lead, which should be the upper limit for lead content according to health experts at Consumer Reports, the

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<sup>&</sup>lt;sup>44</sup> See Nurture, Heavy Metal Test Results for Baby Food Products (Dec. 18, 2019) ("Nurture Test Results"), available at: <a href="http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx">http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx</a>).

<sup>45</sup> Id.

 $<sup>^{46}</sup>$  *Id*.

<sup>&</sup>lt;sup>47</sup> *Id*.

<sup>&</sup>lt;sup>48</sup> *Id*.

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Environmental Defense Fund, and the American Academy of Pediatrics. <sup>49</sup> The average amount of inorganic arsenic in the baby foods that Nurture tested and sold was 59.54 ppb. That towers over existing and recommended standards, including FDA's and EPA's water limits of 10 ppb. At least 89 of Nurture's final products—over 78% of those products tested—tested at 9 ppb inorganic arsenic or above. For results under 9.54 ppb, Nurture did not differentiate—it marked them all as "<9.54" in its submission to Congress. Because of this "less than" reporting format, there is no way to confirm if any of Nurture's products were free of inorganic arsenic. Nurture sold 125 products that tested over 5 ppb, which is the EPA's limit for drinking water; <sup>50</sup> a finished baby food product that contained 10 ppb mercury; and two others that contained 9.8 and 7.3 ppb. A level of 10 ppb is five times more than the EPA's 2 ppb standard for mercury drinking water. In total, Nurture sold 56 products that contained over 2 ppb mercury.

- 2. Nurture Willfully and Recklessly Disregards Internal and Regulatory Standards for Toxic Heavy Metals in is Baby Food.
- 38. Nurture created internal standards but did not follow them. Nurture describes these standards as "goal thresholds" that "are not used to make product disposition decisions and are not a pre-condition to product release." Instead, its testing regime is limited to monitoring the supply chain as opposed to ensuring that babies are not exposed to Toxic Heavy Metals. Nurture's thresholds are not actually used to prevent products that contain high levels of Toxic Heavy Metals from being sold. 52

<sup>&</sup>lt;sup>49</sup> See Consumer Reports, Consumer Reports letter to FDA on reducing heavy elements like arsenic, lead, and cadmium in fruit juices (January 2019), available at: https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-

elements-like-arsenic-lead-and-cadmium-in-fruit-juices/; ED, FDA's outdated Lead Standards Put the Public's Health at Risk (December, 9 2020), available at: <a href="https://www.edf.org/media/fdas-outdated-lead-standards-put-publics-health-risk">https://www.edf.org/media/fdas-outdated-lead-standards-put-publics-health-risk</a>; American Academy of Pediatrics, Lead Exposure in Children (2016), available at: <a href="https://www.aap.org/en-us/advocacy-and-policy/aap-health-">https://www.aap.org/en-us/advocacy-and-policy/aap-health-</a>

<sup>&</sup>lt;u>initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx</u>.

<sup>&</sup>lt;sup>50</sup> See Nurture Test Results, supra.

<sup>&</sup>lt;sup>51</sup> Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) ("Letter from Nurture") at 3, available at: <a href="https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf">https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf</a>).
<sup>52</sup> Id. at 3-4.

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39. Nurture does not even claim to be testing for safety—in its letter response to the Congressional investigation, Nurture stated: "our heavy metal testing is performed as part of our monitoring program and not as a condition of product release, all of the products that were tested were sold into commerce."53 Nurture sells the products it tests, regardless of their toxic heavy metal content. In total, Nurture tested 113 final products and sold every product tested, regardless of how much inorganic arsenic or lead the product contained, and regardless of whether those metals exceeded its own internal standards. As a result of this policy of not testing for safety, Nurture released products containing as much as 641 ppb lead and 180 ppb inorganic arsenic.<sup>54</sup> Nurture sold 29 products that were above its internal arsenic limit of 100 ppb, including Apple & Broccoli Puffs that contained 180 ppb inorganic arsenic. Further, Nurture appears to have misled the Congressional investigation about its testing standards. Nurture conveyed to the Subcommittee that after January of 2019, it had a goal threshold of 50 ppb for lead in all of its baby food products—infant formula, cereals, and wet foods. 55 However, after the date Nurture claims to have moved to a 50 ppb lead standard—January 2019—Nurture was still using a "Goal Threshold" of 100 ppb for 53 baby food products, as demonstrated by Nurture's internal tests.<sup>56</sup> Nurture blatantly lied to Congress about these results. And, Nurture has also ignored the only final standard that FDA has set for heavy metals in Baby Foods: 100 ppb inorganic arsenic limit for infant rice cereal. Rather than comply with that limit, Nurture set its internal standards 15% higher, at 115 ppb inorganic arsenic.<sup>57</sup>

## B. Gerber Regularly Uses Ingredients High in Toxic Heavy Metals in its Baby Food

40. Test results for conventional rice flour revealed that Gerber routinely uses flour with over 90 ppb inorganic arsenic.<sup>58</sup> Gerber used five batches of rice flour that had 98 ppb inorganic arsenic, and 67 batches that contained more than 90 ppb. <sup>59</sup> The results for Gerber sweet potatoes and

<sup>&</sup>lt;sup>53</sup> *Id*. at 4.

<sup>&</sup>lt;sup>54</sup> Nurture Test Results, *supra*.

<sup>&</sup>lt;sup>55</sup> Letter from Nurture at 1, 3.

<sup>&</sup>lt;sup>56</sup> Nurture Test Results, *supra*.

<sup>&</sup>lt;sup>57</sup> Letter from Nurture at 3.

<sup>&</sup>lt;sup>58</sup> Gerber, Gerber Products Company Test Results (Dec. 9, 2019) ("Gerber Tests"), available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5\_0.pdf). <sup>59</sup> *Id.* at \*3-4, 7.

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# juices demonstrated its willingness to use ingredients that contained dangerous lead levels. Gerber used an ingredient, conventional sweet potatoes, with 48 ppb lead and twelve other batches of sweet potato that tested over 20 ppb for lead, the EU's lenient upper standard. The average amount of lead in Gerber's tested juice concentrates was 11.2 ppb—more than FDA's limit for lead in bottled water. Over 83% of the juice concentrates tested showed greater than 1 ppb lead, which is Consumer Reports' recommended limit for fruit juices. Gerber only tests certain ingredients for mercury. Of the test results Gerber presented to the Subcommittee, it only tested carrots, sweet potatoes, and lemon juice concentrate.

## V. Exemplary / Punitive Damages Allegations

- 41. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants' conduct is particularly reprehensible given that their toxic foods were directed at vulnerable babies—a population group far more susceptible than adults to the neurotoxic dangers of heavy metals.
- 42. Defendants were fully aware of the safety risks of Baby Foods, particularly the dangerous potential of their Baby Foods due to the presence of substantial Toxic Heavy Metals that have all been associated with neurodevelopmental disorders in children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to mislead consumers. Indeed, Defendants repeatedly market their Baby Foods as safe for consumption and go so far as claiming that they adhere to "rigorous safety protocols" and provide "highest standards" as well as other statements and representations that hold out their Baby Foods as safe for consumption by infants. In actual fact, as discussed above, Defendants routinely sold Baby Foods containing astronomical amounts of Toxic Heavy Metals, regularly flouted their own internal limits of Toxic Heavy Metals in Baby Foods and failed to disclose to consumers that their products contained such dangerous contaminants.
- 43. This was not done by accident or through some justifiable negligence. Rather,

  Defendants knew they could profit by convincing consumers that their Baby Foods were harmless to

 $<sup>\</sup>int_{0}^{60} Id$ . at \*16,

<sup>&</sup>lt;sup>61</sup> *Id*. at \*9-11.

<sup>&</sup>lt;sup>62</sup> *Id.* at \*15, 16, 18, 22-24.

humans, and that full disclosure of the true risks of the Toxic Heavy Metals present in the Baby Foods would limit the amount of money Defendants would make selling the products. Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, failure to test, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Parents were denied the right to make an informed decision about whether to purchase and Defendants' Baby Food for their children, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

44. Accordingly, Plaintiff requests punitive damages against Defendants for the harms caused to Plaintiff.

## **PLAINTIFF-SPECIFIC ALLEGATIONS**

- 45. Plaintiff was diagnosed with ASD in February 2021 at 3 years and 2 months of age.
- 46. Plaintiff started consuming the below-identified Baby Food products in approximately 2018 and continued to consume the below-identified Baby Food products at various times until approximately 2020.
- 47. Plaintiff consumed substantial quantities of the Baby Food products manufactured by Defendants, consuming the foods on a daily basis.
- 48. Plaintiff has not finished his investigation of the case. Accordingly, the Baby Foods identified below may not be exhaustive of the products manufactured by Defendants and consumed by Plaintiff:

Nurture (HappyFamily). Greek Yogis Strawberry; Greek Yogis Mixed Berry; Greek Yogis Blueberry & Purple Carrot; Snackers Creamy Spinach & Carrot; Creamies Apple, Spinach, Pea & Kiwi; Creamies Strawberry, Raspberry & Carrot; Teethers Sweet Potato & Banana; Food Pouches: Stage 2 Apples, Spinach & Kale; Stage 2 Apples, Kale & Avocados; Stage 2 Carrots, Strawberries & Chickpeas; Stage 4 Pears, Raspberries, Carrots & Butternut Squash; Stage 4 Pears, Kiwi & Kale; Stage 2 Pears, Zucchini & Peas; Stage 2 Pears, Zucchini & Peas. Food Bars: Apple + Cinnamon Fruit & Oat; Blueberry & Raspberry Fruit & Oat. Superfood Puffs: Apple & Broccoli; Kale & Spinach; Banana & Pumpkin; Strawberry & Beet.

49. Upon information and belief, the Baby Food products identified above manufactured

by Nurture and consumed by Plaintiff were all contaminated with substantial quantities of Toxic Heavy Metals, namely arsenic, mercury, and lead—exceeding that of any regulatory limits.

- 50. Upon information and belief, as a direct and proximate result of consuming Nurture's Baby Foods, Plaintiff was exposed to substantial quantities of Toxic Heavy Metals, namely mercury, lead, and arsenic.
- 51. As a direct and proximate result of consuming Nurture's Baby Foods—and exposure to the Toxic Heavy Metals therein—Plaintiff was diagnosed with ASD.

<u>Gerber.</u> Arrowroot Biscuits; **Puff Snacks**: Blueberry Puffs; Cranberry Orange Organic Puffs; Organic Lil' Crunchies White Bean Hummus; Organic Lil' Crunchies White Cheddar Broccoli; Sweet Potato Puffs; Vanilla Puffs.

- 52. Upon information and belief, the Baby Food products identified above manufactured by Gerber and consumed by Plaintiff were all contaminated with substantial quantities of Toxic Heavy Metals, namely arsenic, mercury, and lead—exceeding that of any regulatory limits.
- 53. Upon information and belief, as a direct and proximate result of consuming Gerber's Baby Foods, Plaintiff was exposed to substantial quantities of Toxic Heavy Metals, namely mercury, lead, and arsenic.
- 54. As a direct and proximate result of consuming Gerber's Baby Foods—and exposure to the Toxic Heavy Metals therein—Plaintiff was diagnosed with ASD.
- 55. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at the levels contained in Defendants' Baby Foods can cause ASD in humans.
- 56. Had any Defendant warned Plaintiff's parents that Defendants' Baby Foods could lead to exposure to Toxic Heavy Metals or, in turn, ASD, Plaintiff would not have consumed the Baby Foods.
- 57. Plaintiff alleges that as a direct and proximate result of Plaintiff's consumption of Baby Foods manufactured by Defendants, Plaintiff suffered significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to ASD and other *sequelae*.

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## **CAUSES OF ACTION**

#### COUNT I: STRICT PRODUCTS LIABILITY - FAILURE TO WARN

- 58. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.
- 59. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and promoting Baby Foods, which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Baby Foods and Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Baby Foods and aimed at a consumer market.
- 60. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their Baby Foods, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the consumption of Baby Foods.
- 61. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or distributor of food, are held to the knowledge of an expert in the field.
- 62. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Baby Foods because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.
- 63. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed by Defendants' Baby Foods.

- 64. Even though Defendants knew or should have known that Baby Foods posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the neurotoxic characteristics of Toxic Heavy Metals contained in Defendants' Baby Foods, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiff. The product warnings for Baby Foods in effect during the time period Plaintiff consumed Baby Foods were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert consumers to the severe health risks associated with Baby Foods consumption.
- 65. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, of the risks of exposure to their products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods to expose children to Toxic Heavy Metals, and further, have made false and/or misleading statements concerning the safety of Baby Foods.
- 66. At all relevant times, Defendants' Baby Foods reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.
- 67. Plaintiff was exposed to Defendants' Baby Foods without knowledge of their dangerous characteristics.
- 68. At all relevant times, Plaintiff was exposed to Defendants' Baby Foods while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.
- 69. Plaintiff could not have reasonably discovered the defects and risks associated with Baby Foods prior to or at the time of Plaintiff consuming Baby Foods. Plaintiff relied upon the skill,

superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

- 70. Defendants knew or should have known that the information disseminated with their Baby Foods were inadequate, failed to communicate adequate information on the dangers consumption, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.
- 71. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid consuming the products. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to aggressively promote the safety of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of consuming Baby Foods.
- 72. This alleged failure to warn is not limited to the information contained on Baby Foods labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Baby Foods through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any medium. The ability to provide such warnings is not prohibited by any federal law.
- 73. Furthermore, Defendants possess a First Amendment Right to make truthful statements about the products they sell, and no law could lawfully restrict that constitutional right.
- 74. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative products. However, as a result of Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted his injuries.

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babies and children, including Plaintiff, with knowledge of the safety problems associated with Baby Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

76. The Defendants' lack of adequate warnings and instructions accompanying their Baby

Defendants' conduct, as described above, was reckless. Defendants risked the lives of

- 76. The Defendants' lack of adequate warnings and instructions accompanying their Baby Foods were a substantial factor in causing Plaintiff's injuries.
- 77. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.
- 78. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

#### COUNT II: STRICT PRODUCTS LIABILITY - DESIGN DEFECT

- 79. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.
- 80. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, and distributed the Baby Foods consumed by Plaintiff. These actions were under the ultimate control and supervision of Defendants.
- 81. At all relevant times, Defendants' Baby Food products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to infants and babies, including Plaintiff.
- 82. Defendants' Baby Food products as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they were placed into the stream of commerce, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

- 83. Defendants' Baby Food products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants', the foreseeable risks exceeded the alleged benefits associated with their design and formulation.
- 84. At all relevant times, the Baby Food products consumed by Plaintiff were expected to and did reach Plaintiff without a substantial change in their condition as manufactured, handled, distributed, and sold by Defendants.
- 85. At all relevant times, Defendants knew or had reason to know that their Baby Food products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.
- 86. Therefore, at all relevant times, Defendants' Baby Food products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

When placed in the stream of commerce, Defendants' Baby Food products were unreasonably dangerous in that they were hazardous and posed a grave risk of neurodevelopmental disorders—specifically ASD—when used in a reasonably anticipated manner due to the substantial quantities of Toxic Heavy Metals in the Baby Foods; when placed in the stream of commerce, Defendants' Baby Food products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner; Defendants did not sufficiently test, investigate, or study their Baby Food products; exposure to the Toxic Heavy Metals in Defendants' Baby Food products presents a risk of harmful effects that outweigh any potential utility stemming from their use; Defendants knew or should have known at the time of marketing Baby Food products that exposure to their Baby Food products could result in neurodevelopmental disorders—specifically ASD—in children; Defendants did not conduct adequate post-marketing surveillance of their Baby Food products; and Defendants could have employed safer alternative designs and formulations.

87. Plaintiff consumed Defendants' Baby Food products in an intended or reasonably foreseeable manner without knowledge of their dangerous characteristics.

- 88. Defendants' Baby Food products were and are more dangerous than alternative products, and Defendants could have designed their Baby Food products to avoid harm to children. Indeed, at the time Defendants designed the Baby Food products, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable, as demonstrated by the fact that other manufacturers of baby foods sell products without the dangerous presence of Toxic Heavy Metals.
- 89. At the time the Baby Food products left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods.
- 90. Defendants have intentionally and recklessly defectively designed the Baby Foods with wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their economic interests above the health and safety of the Plaintiff.
- 91. The design defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.
- 92. As a direct and proximate result of the Defendants' defective design of the Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

**WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

## COUNT III: STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT

- 93. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.
- 94. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, and distributed the Baby Foods consumed by Plaintiff.
- 95. At all relevant times, the Baby Foods consumed by Plaintiff were expected to and did reach Plaintiff without a substantial change in their condition as manufactured, handled, distributed,

and sold by Defendants.

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- 96. At all relevant times, the Baby Foods consumed by Plaintiff were used in a manner that was foreseeable and intended by Defendants.
- 97. The Baby Foods consumed by Plaintiff were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design and manufacturing specifications and/or such design and manufacture posed an unreasonable risk of harm to Plaintiff.
- 98. The Defendants' Baby Foods are inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and do not meet or perform to the expectations of parents or children.
- 99. The Baby Foods create risks to the health and safety of babies that are far more significant and devastating than the risks posed by other baby food products, and which far outweigh the utility of the Baby Foods products because of Defendants' manufacturing defects, which included but were not limited to: failure to adequately inspect/test the Baby Foods during the manufacturing process; failure to implement procedures that would reduce or eliminate the levels of Toxic Heavy Metals in Baby Foods; failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to manufacture Baby Foods.
- 100. Defendants have intentionally and recklessly manufactured the Baby Foods with wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their economic interests above the health and safety of the Plaintiff.
- 101. The manufacturing defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.
- 102. As a direct and proximate result of the Defendants' defective manufacture of the Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.
- **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and

further relief as this Court deems just and proper.

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## **COUNT IV: NEGLIGENCE – FAILURE TO WARN**

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Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as

104. At all relevant times, Defendants engaged in the business of testing, developing,

designing, manufacturing, marketing, selling, distributing, and promoting Baby Foods. Defendants

knew or by the exercise of reasonable care should have known that their Baby Foods are not

accompanied with adequate warnings concerning the dangerous characteristics of Baby Foods and

Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants.

105. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Baby Foods, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of Baby Foods.

- 106. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or distributor of food products, are held to the knowledge of an expert in the field.
- 107. At the time of manufacture, Defendants could have provided warnings regarding the full and complete risks of Baby Foods and Toxic Heavy Metals because they knew or should have known use of Baby Foods was dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.
- 108. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed by Defendants' Baby Foods.
  - 109. Defendants knew or should have known that Baby Foods posed a grave risk of harm

but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the characteristics of Toxic Heavy Metals contained in substantial amounts in their Baby Foods, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as the Plaintiff.

- 110. Defendants further breached their duty by failing to use reasonable care to adequately warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods to expose babies and toddlers to Toxic Heavy Metals, and further, have made false and/or misleading statements concerning the safety of Baby Foods.
- 111. At all relevant times, Plaintiff was exposed to excessive levels of Toxic Heavy Metals through consumption of Toxic Heavy Metals while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.
- 112. Defendants knew or should have known that the minimal warnings disseminated with their Baby Foods were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.
- 113. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of consuming Baby Foods.

- 114. A reasonable company under the same or similar circumstance would have warned and instructed of the dangers of Baby Foods and Toxic Heavy Metals contained therein.
- 115. This alleged failure to warn is not limited to the information contained on the labeling of Defendants' Baby Foods. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Baby Foods and Toxic Heavy Metals through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any medium.
- 116. Furthermore, Defendants possess a First Amendment Right to make truthful statements about the products they sell, and no law could lawfully restrict that constitutional right.
- 117. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative products. However, as a result of Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted his injuries.
- 118. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers of their products, including Plaintiff, with knowledge of the safety problems associated with Baby Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.
- 119. The Defendants' lack of adequate warnings and instructions accompanying their Baby Foods were a substantial factor in causing Plaintiff's injuries.
- 120. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.
- 121. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such

other and further relief as this Court deems just and proper.

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#### **COUNT V: NEGLIGENT PRODUCT DESIGN**

- 122. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby Foods.
- 123. The Defendants owed a duty to all reasonably foreseeable users to design a safe product.
- 124. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods because the product exposed users to unsafe levels of Toxic Heavy Metals.
- 125. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods by negligently designing the Baby Foods with ingredients and/or components high in Toxic Heavy Metals.
- 126. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods by negligently designing and formulation, in one or more of the following ways: when placed in the stream of commerce, Defendants' Baby Foods were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate; when placed in the stream of commerce, Defendants' Baby Foods were unreasonably dangerous in that they were hazardous and posed a grave risk of neurodevelopmental disorders and other serious illnesses when used in a reasonably anticipated manner; when placed in the stream of commerce, Defendants' Baby Foods contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner; Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically, the content of Toxic Heavy Metals in the ingredients used to manufacture the foods and/or the finished products; Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically, the ability for Baby Foods to expose babies to high amounts of Toxic Heavy Metals; exposure to Baby Foods presents a risk of harmful effects that outweigh any potential utility stemming from the use of the products; Defendants knew or should have known at the time of marketing Baby Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in neurodevelopmental

disorders—specifically ASD—and other severe illnesses and injuries; Defendants did not conduct adequate post-marketing surveillance of their Baby Foods; and Defendants could have employed safer alternative designs and formulations. For example, Defendants could have avoided use of certain ingredients high in Toxic Heavy Metals, implemented strict and safe internal limits for the presence of Toxic Heavy Metals in their foods, taken care to ensure that the manufacturing process did not result in the substantial presence of Toxic Heavy Metals in their foods, and/or sampled their ingredients from alternative sources.

- 127. The Defendants breached their duty by failing to use reasonable care by failing to use cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods.
- 128. A reasonable company under the same or similar circumstances would have designed a safer product.
- 129. Plaintiff was harmed directly and proximately by the Defendants' failure to use reasonable care in the design of their Baby Foods. Such harm includes significant exposure to a Toxic Heavy Metals, which can cause or contribute to the development of neurodevelopmental disorders such as ASD.
- 130. Defendants' defective design of Baby Foods was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of consumers of the Baby Foods, including Plaintiff.
- 131. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.
- 132. As a direct and proximate result of the Defendants' defective design of the Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.
- 133. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such

other and further relief as this Court deems just and proper.

#### **COUNT VI: NEGLIGENT MANUFACTURING**

- 134. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.
- 135. At all relevant times, the Defendants manufactured, tested, marketed, sold, and distributed the Baby Foods that Plaintiff consumed.
- 136. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing, marketing, sale, and distribution of Baby Foods.
- 137. The Defendants knew or, by the exercise of reasonable care, should have known that their Baby Foods were carelessly manufactured, dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.
- 138. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby Foods improperly manufactured, tested, marketed, distributed, and sold.
- 139. Without limitation, examples of the manner in which Defendants breached their duty to exercise reasonable care in manufacturing Baby Foods, included: Failure to adequately inspect/test the Baby Foods during the manufacturing process; failure to implement procedures that would reduce or eliminate levels of Toxic Heavy Metals in Baby Foods; and failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to manufacture Baby Foods.
- 140. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality and safety of their product.
- 141. Plaintiff was harmed directly and proximately by the Defendants' failure to use reasonable care in the manufacture of their Baby Foods. Such harm includes significant exposure to a Toxic Heavy Metals, which can cause or contribute the development of neurodevelopmental disorder such as ASD.
- 142. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Baby Foods, including

Plaintiff.

- 143. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.
- 144. As a direct and proximate result of the Defendants' improper manufacturing of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.
- 145. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

#### **COUNT VII: NEGLIGENT MISREPRESENTATION**

- 146. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.
- 147. At all relevant times, Defendants designed, manufactured, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed Baby Foods into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that consumed Baby Foods, such as Plaintiff.
- 148. Defendants were negligent, reckless, and careless and owed a duty to Plaintiff to make accurate and truthful representations regarding Baby Foods, Defendants breached their duty, thereby causing Plaintiff to suffer harm.
- 149. Defendants represented to Plaintiff via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations described herein that: Baby Foods were both safe and effective for the lifetime of the product, when in fact, the foods contain unsafe levels of Toxic Heavy Metals far in excess of regulatory and scientific standards; consumption of Baby Foods would not expose babies to any harmful ingredients; and Baby Foods were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose.
  - 150. These representations were false. Because of the presence and/or unsafe levels of

against the Defendants for:

1	a.	actual or compensatory dama	ges in such amount to be determined at trial and as
2		provided by applicable law;	
3	b.	exemplary and punitive damages sufficient to punish and deter the Defendants and	
4		others from future wrongful I	practices;
5	c.	pre-judgment and post-judgm	nent interest;
6	d.	costs including reasonable attorneys' fees, court costs, and other litigation expenses;	
7		and	
8	e.	any other relief the Court ma	y deem just and proper.
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10	Dated: May 2	23, 2022 <b>BAUN</b>	I HEDLUND ARISTEI & GOLDMAN, P.C.
11			<del>- ( ) 2.</del>
12		Pedrar	n Esfandiary, Esq. (SBN 312569)
13		<u>pesfan</u>	diary@baumhedlundlaw.com
14			nt Wisner, Esq. (SBN: 276023) <a href="mailto:er@baumhedlundlaw.com">er@baumhedlundlaw.com</a>
15			Wilshire Blvd., Suite 1600 ngeles, CA 90024
16		Tel: (3	10) 207-3233
17		rax: (3	310) 820-7444
18		Attorn	eys for Plaintiff
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